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10/553,999

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Roland Barten

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EXAMINER

GERIDO, DWAN A

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/553,999 | Applicant(s) BARTEN ET AL. | |
| | Examiner Dwan A. Gerido, Ph.D. | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-21-2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of claims 1-32 in the reply filed on January 9, 2009 is acknowledged. Applicant did not specify whether the election was with or without traverse, therefore applicant's response will be treated as an election without traverse.

Claim Objections

2. Claims 4, 6, 17, 20, 21, and 28 objected to because of the following informalities: claims 4, 6, 17, 20, and 28 have extra spaces between words within the claim. Claim 21 recites "CL)" which is being read as a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7-10, 15, 18, 20, 23, 24, 26, 27, and 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. For claim 7, it is unclear as to what applicant regards as "the second cylinder". For the purposes of examination, the second cylinder will be read as the second chamber.

6. Claims , 8-10, 15, 18, 23, and 24 recite the limitation 'further chamber', it is unclear which chamber(s) applicant regards as a 'further chamber'. For the purposes of examination, 'further chamber' will be read as any chamber downstream of the specific chamber recited in the claims.

7. For claims 18, 20, 23, 24, 27, and 30 it is unclear which chamber applicant is referring to when applicant recites a chamber and 'preferably' a separate chamber or chambers.

8. For claim 26, it is unclear what applicant regards as the surrounding. For the purposes of examination, the surrounding will be read as any material surrounding the connectors.
9. Claim 7 recites the limitation "the second cylinder" in line 2. There is insufficient antecedent basis for this limitation in the claim.
10. Claim 26 recites the limitation "the surrounding" in line 2. There is insufficient antecedent basis for this limitation in the claim.
11. Claim 30 recites the limitation "the edge" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 4-9, 12, 13, 16-20, 23-26, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (US 4,585,623).
14. For claim 1, Chandler teaches a device comprising a first and second chamber connected by a channel (column 2 lines 59-63, column 3 lines 1-3, figure 2 #'s 12, 13, and 20) wherein the first and second chambers have means for reversibly changing their volume (column 3 lines 4-7, figure 7 #15). Chandler also teaches the device comprising a connector with a means for flow regulation connected to the chamber (figure 2). The connector of Chandler reads on the claimed structure in that Chandler recites a plunger with a septum for regulating flow into the chamber.

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15. For claim 2, Chandler recites the device being utilized for diagnostic medical testing (pregnancy test) therefore; it would be designed as a single use device.

16. For claim 4, Chandler teaches a second chamber comprising a means for reversibly changing volume (column 3 lines 4-7).

17. For claim 5, Chandler teaches a first connector connected to the first chamber (figure 1).

18. For claim 6, Chandler teaches a second connector connected to a second channel that extends from the second chamber opposite the second means for changing volume (see chamber 13 in figures 2 and 7).

19. For claim 7, Chandler teaches a second channel connected to the first channel wherein the second channel extends from the second chamber opposite the second piston (figure 2 #'s 13 and 20).

20. For claim 8, Chandler teaches a further chamber having a reversibly changeable volume (column 7 #'s 14, 16-17) wherein the further chambers are connected to the first and second chamber through the first and second channels (figure 2 #20).

21. For claim 9, Chandler teaches a means of flow regulation between the first and second chamber on one side, and at least one further chamber on another side (figure 7 #30).

22. For claims 12, 13, and 16, Chandler teaches the means for changing volume in the chambers as a piston (column 4 lines 4-7, figure 7 #50) wherein the pistons and chambers have identical shapes (circular) and not connected to a piston rod.

23. For claim 17, Chandler teaches the chambers having an essentially round cross-section (figure 2 #'s 12-14, 16, 18).

24. For claim 18, Chandler teaches the chambers connected to the channels (figure 2 #20).

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25. For claim 19, Chandler teaches the axes of the chambers being parallel (figures 1 and 7).
26. For claim 20, Chandler teaches a chamber having a solution that dissolves the substrate which is being read on the claimed solubilizing solution (column 3 lines 60-63).
27. For claim 23, Chandler teaches a chamber having a wash solution (column 3 lines 56-60).
28. For claim 24, Chandler teaches a chamber having an elution solution (column 3 lines 60-63).
29. For claim 25, Chandler teaches the connectors having a valve (figure 7 #30)
30. For claim 26, Chandler teaches the chambers being fluid tight against the surrounding when the connectors are closed (column 3 lines 47-53, figure 1). Claim 26 is being read in light of the 35 U.S.C 112 rejection listed above in that it is unclear what applicant regards as the surrounding.
31. For claim 28, Chandler teaches the device provided with an enclosure made of synthetic material (column 2 lines 25-27, column 5 lines 29-37).
32. For claim 29, Chandler teaches the channels and connectors in a base plate (figure 2).

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

34. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

35. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

36. Claims 3, 10, 11, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 4,585,623).

37. With regards to claim 3, Chandler does not teach a device wherein no means of flow regulation is provided between the first and second chamber. It is advantageous to remove a means of flow regulation between the first and second chamber as a means of allowing a reagents to flow freely between the two chambers. Additionally, the MPEP states that it is obvious to omit an element where the function of said element is not desired or required (MPEP 2144.04 II A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler wherein there is no means of flow regulation between the first and second chambers as omission of an element requires only routine skill in the art.

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38. With regards to claim 10, Chandler teaches a waste chamber with a flexible membrane to accommodate an increased volume between two chambers (column 3 lines 18-29, figures 5-7, #'s 35 and 36). Chandler teaches that it is advantageous to utilize a waste chamber with a flexible membrane to remove the need of a vent for the waste reservoir. Chandler does not explicitly teach the volume of the waste chamber being larger than the total compressible volume of the system; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler wherein the waste chamber has a volume larger than the total volume of the system in order to accommodate the volume of fluid waste and to remove the need for a vent within the waste reservoir as taught by Chandler.

39. With regards to claim 11, Chandler does not teach the device wherein the chambers are conically tapered at the end of the chamber. This feature is being read as a change in shape as applicant does not offer evidence to show that a conical structure overcomes that of the prior art. In addition, the MPEP states that changes in shape are a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler wherein the chambers have a conically tapered shape as changes in shape require only routine skill in the art.

40. With regards to claim 32, Chandler does not explicitly teach the components in a kit; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the components within a kit to attain the commercial advantage of providing the components of the device in a single package.

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41. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 4,585,623) in view of Kimura (US 5,484,734).

42. With regards to claim 14, Chandler does not teach the pistons of the first and/or second chambers comprising an elastic material.

Kimura teaches a reaction vessel wherein the pistons are composed of an elastic material (column 2 lines 42-52). Kimura teaches that it is advantageous to form the piston from an elastic material as a means of preventing evaporation by forming a seal between the piston and vessel wall. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Kimura to utilize a piston composed of an elastic material in order to prevent evaporation of reagents within a chamber as taught by Kimura.

43. With regards to claim 15, Chandler does not teach pistons made from an elastic material, thus the pistons of further chambers as taught by Chandler would exhibit a reduced elasticity compared to the piston of the first and/or second chambers as taught by Chandler in view of Kimura.

44. Claims 21, 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 4,585,623) in view of Schnipelsky et al., (US 5,229,297).

45. With regards to claims 21 and 22, Chandler does not teach magnetic particles within the chambers and/or the channels.

Schnipelsky et al., teach a containment cuvette wherein magnetic particles are utilized for binding reaction products (column 17 lines 4-17). Schnipelsky et al., do not teach a specific diameter range for the magnetic beads; however, magnetic beads with small diameters are well

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known in the art, and applicant's ranges are sufficiently broad that one of ordinary skill would have found the claimed diameter ranges obvious. Schnipelsky et al., teach that it is advantageous to utilize magnetic beads as a means of separating the desired reaction products. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Schnipelsky et al., to utilize magnetic beads in order to efficiently separate reaction products from undesired reagents as taught by Schnipelsky et al.

46. With regards to claim 27, Schnipelsky et al., teach applying a magnetic field below the compartment (column 17 lines 18-24) which is being read on the claimed positioning of a magnet at the end of the chamber.

47. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 4,585,623) in view of Holtzman (US 4,889,692).

48. With regards to claim 30, Chandler does not teach the chambers open towards an edge of the enclosure.

Holtzman teaches a disposable sample preparation chamber wherein the chambers have open ends towards the edge of the chamber (column 2 lines 44-46, 49-53, figure 1 #11, A, B, C, D, E, F). Holtzman also teaches the enclosure attached to a device to allow automatic changing of volume of at least one chamber (column 3 lines 26-51). It is advantageous to provide an enclosure as a means of arranging the chambers during operation and protecting the chambers when the device is being transported. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Chandler in view of Holtzman to utilize an enclosure in order to properly arrange the chambers prior to sample preparation.

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49. With regards to claim 31, Holtzman teaches the enclosure with a means for attaching the device to a corresponding receptacle to allow automatic changing of the volume of at least one chamber (column 3 lines 26-51, figure 1 #'s 11, 14, and 28).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

DAG